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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/375,248	08/16/99	FERRELL R	28967/35255A

HM12/1204

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EXAMINER	
SORBELLO,E	
ART UNIT	**PAPER NUMBER**
1633	10

DATE MAILED: 12/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/375,248	FERRELL ET AL.	
	Examiner	Art Unit	
	Eleanor Sorbello	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *30days* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-11 and 14-21 drawn to a method of screening subjects developing a lymphatic disorder classified in class 424, subclass 9.2.

   II. Claim 12, drawn to protein therapy using VEGF-C or VEGF-D, classified in class 514, subclass 2.

   III. Claim 12, drawn to gene therapy using VEGF-C or VEGF-D, classified in class 514, subclass 44.

   IV. Claims 13 and 22-29, drawn to a polynucleotide encoding VEGF-3, vectors, host cells, and methods using ex-vivo therapy classified in class 514, subclass 44.

   V. Claims 30-36, drawn to methods of identifying a modulator, classified in class 435, subclass 6.

2. Inventions I, II, III, IV and V are related as they are all drawn to methods. However inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions I - V have distinct modes of operation, different functions, different effects and are not capable of being used together.

3. Invention I is distinct from Invention II, III, IV, and V, because of the following reasons: Invention I is drawn to a method of screening human subjects for an increased risk of developing a lymphatic disorder; Invention II is drawn to a method of treatment of hereditary lymphedema using protein therapy using VEGF-C or VEGF-D; Invention III is drawn to a method of treatment of hereditary lymphedema using gene therapy wherein nucleotides encoding VEGF-C or VEGF-D are used; Invention IV is drawn to ex vivo methods of treatment using polynucleotides encoding VEGF-3; and Invention V is drawn to a method of identifying modulators of intracellular VEGF-3. Hence Invention I is distinct from Invention II, III, IV and V as they are distinct methods and are not shown to be capable of being used together. The steps and essential elements for using the methods are not the same.

4. Invention II is distinct from Invention III, IV and V because of the following reasons: Invention II is drawn to a method of treatment of hereditary lymphedema using protein therapy using VEGF-C or VEGF-D; Invention III is drawn to a method of treatment of hereditary lymphedema using gene therapy wherein nucleotides encoding VEGF-C or VEGF-D are used; Invention IV is drawn to ex vivo methods of treatment using polynucleotides encoding VEGF-3; and Invention V is drawn to a method of identifying modulators of intracellular VEGF-3. Hence Invention II is distinct from Invention III, IV and V as they are distinct methods and are not shown to be capable of being used together. The steps and essential elements for using the methods are not the same.

5. Invention III is distinct from Invention IV and V, because of the following reasons: Invention III is drawn to a method of treatment of hereditary lymphedema using gene therapy wherein nucleotides encoding VEGF-C or VEGF-D are used; Invention IV is drawn to ex vivo methods of treatment using polynucleotides encoding VEGF-3; and Invention V is drawn to a method of identifying modulators of intracellular VEGF-3. Hence Invention III is distinct from Invention IV and V as they are distinct methods and are not shown to be capable of being used together. The steps and essential elements for using the methods are not the same.

6. Invention IV is distinct from Invention V, because of the following reasons: Invention III is drawn to a method of treatment of hereditary lymphedema using gene therapy wherein nucleotides encoding VEGF-C or VEGF-D are used; Invention IV is drawn to ex vivo methods of treatment using polynucleotides encoding VEGF-3; and Invention V is drawn to a method of identifying modulators of intracellular VEGF-3. Hence Invention IV is distinct from Invention V as they are distinct methods and are not shown to be capable of being used together. The steps and essential elements for using the methods are not the same.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and require a different search strategy, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, III, IV or V restriction for examination purposes as indicated is proper.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleanor Sorbello on (703-308-6043). The examiner can normally be reached on Mondays-Fridays from 6.30 a.m. to 3.00p.m. EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached on (703)-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

November 27, 2000

DEBORAH J. R. CLARK
SUPERVISORY PATENT EXAMINER
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